

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Patent Application of

Chiu, et al.

Serial No. 07/525,943

Filed: May 17, 1990

For: BULKING AGENTS AND PROCESSES FOR
PREPARING THEM FROM FOOD GUMS

Group Art Unite: 1302

Examiner: J. Gollan

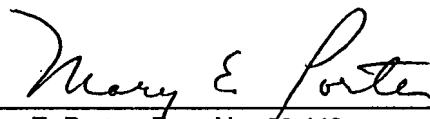
LETTER

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Washington, D.C. 20231

Sir:

Enclosed please find Appellants' Appeal Brief, in triplicate, in the above-captioned patent application.

Respectfully submitted,



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December 16, 1993

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20231, ON December 17, 1993
BY Mary E. Porter

APPEAL BRIEF

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The claims on appeal, Claims 29-35, are set forth in Appendix A that is annexed to this Brief.

Status of Amendment

All amendments submitted by Appellants have been entered and are represented by the claims in Appendix A.

Summary of the Invention

Appellants claim edible formulations, comprising water soluble hydrolysates of food gums having a weight average molecular weight of 500 to 50,000, an average degree of polymerization ("DP") of 3 to 75 and a maximum viscosity of 50 cps in a 30% solution. Appellants claims are limited to hydrolysates of a selected group of food gums, including guar gum, locust bean gum, konjac gum, xanthan gum, pectin, carrageenan and alginates, and combinations thereof. Claim 1.

In a preferred embodiment of the edible formulation, the food gum hydrolysate is substantially non-digestible. Claim 30. Specific edible formulations containing the food gum hydrolysates as bulking agents include baked goods, puddings, creams and custards, jams and jellies, confections, soft drinks and other sweetened beverages, in liquid or dry form, sauces and salad dressings, ice cream and frozen desserts, and pharmaceuticals. Claim 33.

The food gum hydrolysates useful as bulking agents are particularly suitable for use in edible formulations which are sweetened with non-nutritive sweeteners, such as aspartame, or its salts or metal complexes, acesulfane-K, alitame, trichlorogalactosucrose, cyclamates, saccharin, fructose, neohesperidine, and mixtures thereof. Claims 32 and 34.

Appellants also claim a method for providing non-nutritive bulk to edible products, comprising the steps of depolymerizing a food gum selected from guar gum, locust bean gum, konjac gum, xanthan gum, pectin, carrageenan and alginates, and combinations thereof, to form a bulking agent, and substituting the depolymerized food gum for 0.5 to 100% of at least one nutritive component of the edible product. The benefit of this method is that the edible product containing the depolymerized food gum is characterized by the physical, organoleptic and non-sweetening functional attributes (e.g., texture, bulk and structure) of the nutritive component for which it was substituted. Claim 35.

The benefit of the hydrolyzed food gum when used as a bulking agent in edible products or formulations is that it permits formulation of foods having reduced caloric content without loss of functional attributes contributed by nutritive components. For example, in the case of sugar, sugar provides body, viscosity and mouthfeel in liquids, contributes to volume, cell structure, crumb structure and humectancy in baked goods and contributes to the overall visual, textural and taste impact of a variety of foods and other edible formulations. See page 1, lines 16-22 of Appellants specification (hereinafter, "Appellants, page __, line __"). In addition, sugar depresses the freezing point and increases the boiling point of foods. The bulking agents known in the art for their utility as a substitute for sugar in foods have various deficiencies which render the food functionally deficient in the absence of sugar. Appellants, page 2, lines 1-27. The

edible formulations claimed in Claims 29-35 are not characterized by these deficiencies.

Issues

1. Whether Claims 29-35 are patentable under 35 USC Section 102(e) over U.S. Patent No. 4,971,814, Issued November 20, 1990 to Tomita, et al., ("Tomita").
2. Whether Claims 29-35 are patentable under 35 USC Section 103 over Tomita.
3. Whether Appellants' two affidavits submitted under 37 CFR Section 1.131 are sufficient to antedate and remove a U.S. patent reference cited under 35 USC Sections 102(e) and 103.
4. Whether Section 715.03 of the Manual of Patent Examining Procedure is consistent with the law of the Court of Appeals for the Federal Circuit ("CAFC").
5. Whether Claims 29-35 are patentable under 35 USC Section 103 over U.S. Patent No. 3,901,874, Issued August 26, 1975 to Hill ("Hill"), in view of European Patent Application Publication No. 0 301 440, published February 1, 1989, by Barnett, et al. ("Barnett").

Grouping of Claims

Appellants consider each Claim under appeal herein to be separately patentable. Claim 29 is an Independent claim directed to edible formulations comprising food gum hydrolysates prepared from a selected group of gums, including guar gum, locust bean gum, konjac gum, xanthan gum, pectin, carrageenan and alginates, and combinations thereof, with the further limitations that the food gum hydrolysates must have a weight average molecular weight of 500 to 50,000, an average DP of 3 to 75 and a maximum viscosity of 50 cps in a 30% solution, and the food gum hydrolysates are effective to function as bulking agents in edible formulations.

Dependent Claim 30 is directed to a separately patentable invention, wherein the edible formulation of Claim 29 contains food gum hydrolysates which are substantially non-digestible. This is an additional functional limitation which is patentably distinct from those set forth in Claim 29.

Claims 31 and 32 are directed to separately patentable edible formulations which are sweetened by a combination of a substantially non-digestible food gum hydrolysate of the type described in Claim 29, together with one or more non-nutritive sweeteners selected from a defined group of sweeteners having fewer calories than sucrose.

Claim 33 is a separately patentable definition of preferred edible formulations which advantageously contain the hydrolyzed food gums described in Claim 29. Claim 30 sets forth a defined subclass of the edible formulations claimed in Claim 29.

Claim 34 depends from Claim 33 and these claims constitute a group which is separately patentable. Claim 34 defines various non-nutritive sweeteners useful in the enumerated edible formulations of Claim 33.

Claim 35 is a separately patentable method of providing non-nutritive bulk to edible products. In

this method, the hydrolyzed food gums of the type described in Claim 29 are prepared by depolymerizing food gums selected from a defined group of seven gums such that the hydrolyzed food gum has the appropriate physical characteristics. This defined hydrolyzed food gum is then substituted for a least one nutritive component of the edible product such that the edible product has physical, organoleptic and non-sweetening functional benefits normally contributed by the nutritive component for which the hydrolyzed food gum was substituted.

Thus, Claim 29, Claim 30, Claims 31-32, Claims 33-34 and Claim 35 constitute claims or groups of claims which each are separately patentable over the art.

ARGUMENT

1. **Claims 29-35 are Patentable Under 35 USC Section 102(e) over U.S. Patent No. 4,971,814, issued November 20, 1990 to Tomita, et al. ("Tomita")**

The Tomita patent discloses dietary fibers having average molecular weight of 2,000 to 15,000. The fibers are prepared by partially hydrolyzing Konnyaku (konjac) powder polysaccharides with an enzyme, yielding a product which is soluble in water, does not prevent absorption of useful minerals in the digestive tract and does not cause diarrhea when consumed in excessive amounts. Tomita also discloses that the hydrolyzed dietary fibers have the beneficial health effects of the untreated Konnyaku powder, but do not have the adverse metabolic affects of the unrefined powder, such as diarrhea and decrease in calcium absorption from the digestive tract when consumed in the diet. See Tomita, columns 1 and 2.

Tomita exemplifies the use of the hydrolyzed dietary fiber at 5.5% in frozen confectionery (average fiber molecular weight of 15,000), at 7% in cookies (average fiber molecular weight 7,000), at 38% in bread (average fiber molecular weight 2,000), and at 5% in juice and milk (average fiber molecular weight 15,000. See Tomita, columns 6-9. None of Tomita's examples show food products containing non-nutritive sweeteners, such as claimed in Appellants Claims 31, 32 and 34. In each of Tomita's food products the hydrolyzed Konnyaku powder is added as a further ingredient and NOT used in place of a traditional nutritive ingredient (e.g., sucrose).

In exemplifying the use of the hydrolyzed dietary fiber in foods, Tomita makes no distinction among functional properties of foods containing fibers of a molecular weight of 2,000, 7,000 or 15,000, thereby teaching that the molecular weight and, therefore, the degree of polymerization (DP) are not critical to the disclosed invention. Tomita discloses no information about the viscosity of the hydrolyzed dietary fibers.

Furthermore, Tomita discloses nothing about the replacement of sugar and other functional ingredients in foods and to the use of the hydrolyzed dietary fiber as a bulking agent. Tomita's disclosure is directed solely to the health benefits of a fiber source. Tomita hydrolyzes the dietary fiber so that negative health consequences of ingestion of dietary fiber in its isolated form are avoided. These negative aspects include a decrease in mineral bioavailability and a change in the osmotic pressure of the digestive tract

resulting in diarrhea following ingestion of the polysaccharide gum.

Although Tomita works with a raw material similar to those used by Appellants (Konnyaku and konjac are assumed to be the same plant), Tomita does not disclose that a hydrolyzed konjac gum, nor any other hydrolyzed food gum may be useful as a functional replacement (non-sweetening) for sugar in foods, or as a functional bulking agent useful in the manufacture of processed foods. Moreover, Appellants identified that the functional utility of the hydrolyzed food gums was limited to hydrolysates having a DP of 3 to 75, preferably a DP of 3 to 30. The functional utility of the hydrolysates are further limited to the viscosity range cited in the claims, a maximum viscosity of 50 cps in a 30% solution. The viscosity limitation must be combined with the weight or DP range because the source of the food gum hydrolysate will alter the relationship between molecular weight or DP and viscosity in solution or dispersion. For example, locust bean gum has a lower viscosity than guar gum. A higher molecular weight locust bean gum hydrolysate would be acceptable in a particular food application which would be deleteriously affected by the addition of a hydrolyzed guar gum having the same molecular weight as the hydrolyzed locust bean gum.

Thus, Tomita is silent with respect to a critical limitation of Appellants' claims on appeal. For this reason, the rejection of Claims 29, 30, 33 and 35 under Section 102(e) over Tomita should be reversed. In addition, because Tomita makes no disclosure with respect to non-nutritive sweeteners, nor the replacement of nutritive ingredients, Claims 31, 32 and 34 are also novel.

2. **Whether Claims 29-35 are Patentable Under 35 USC Section 103 over Tomita.**

Appellants' invention is a result, in part, of a recognition that the depolymerization of a hexose monosaccharide backbone polymer selected from heteropolysaccharides occurring in nature would provide a class of safe, functionally effective, bulking agents suitable for use as a replacement for sucrose and other nutritive components of processed foods. Such substrate materials are commonly understood to be food gums, for example the seven food gums named in Appellants' Claim 29 and Claim 35. These food gum substrates are desirable because food gums have a proven record of safety in foods for human consumption and they have more desirable functional characteristics, with, or without, hydrolysis than common plant fiber sources and other conventional bulking agents, such as microcrystalline cellulose. Microcrystalline cellulose is characterized by a grittiness in residual mouth feel when used as a bulking agent in many food products. Appellants, pages 1-3 and page 4, lines 1-3. The bulking agents used in the claimed edible formulations do not have these undesirable characteristics, because they are prepared by depolymerization of selected heteropolysaccharide gums to form hydrolysates which have a DP of 3 to 75 and are substantially non-digestible following depolymerization. Thus, these bulking agents also may be contrasted with homopolysaccharides, such as starch, or with sugars, which are substantially digestible and provide caloric content as well as bulk to foods.

In teaching that a single type of polysaccharide may be hydrolyzed to avoid negative biological

effects, Tomita suggests nothing with respect to Appellants' identification of a class of hydrolyzed food gums having hitherto unrecognized functional utility in foods. The respective utilities do not suggest one another. However, as described below, armed with the knowledge that a group of heteropolysaccharide food gums have been hydrolyzed to provide bulking agents having excellent functional characteristics, one skilled in the art would be led to add the hydrolyzed Konnyaku polysaccharide taught by Tomita to the human diet.

Furthermore, the disclosures of Tomita do not suggest that any particular viscosity characteristic of the hydrolyzed Konnyaku polysaccharide may be critical to a commercially acceptable edible formulation which would be purchased and consumed in lieu of an equivalent edible formulation containing sucrose or other nutritive ingredients. Appellants' data in Tables III and IV and Example 12, pages 24-28, demonstrate that the bulking agent's viscosity in aqueous dispersion, molecular size and weight of the bulking agents, and the amount of food gum depolymerization are critical limitations to the utility of the bulking agents as functional replacements for sugar in foods.

For example, Table III shows that depolymerized guar gum having a viscosity in a 30% solution of 2,500 cps yields a cake with unacceptable quality. Appellants, page 25, lines 15-31, and page 26, lines 1-27. The same guar gum sample also contains 15.9%, by weight, of fragment having a weight average molecular weight of more than 10,000. Similar results are shown for depolymerized guar gum used to make puddings. Appellants, page 26, lines 29-40, and pages 27-28. Not only does Tomita fail to disclose this fact, but Tomita suggests that the hydrolyzed Konnyaku polysaccharide is acceptable in foods across the entire molecular weight range of 2,000 to 15,000. Tomita does not even provide any viscosity information for the hydrolyzed polysaccharide.

For these reasons, Appellants' claimed invention is not obvious over the disclosure of the Tomita patent.

3. Appellants' Two 37 CFR Section 1.131 Affidavits are Adequate to Antedate and Remove the Tomita Reference.

Appellants responded to the Examiner's rejection of Claims 35-29 over the Tomita reference by presenting the arguments in parts 1 and 2 above, to distinguish the claimed invention over the reference.

In addition, for the purpose of antedating and removing the Tomita patent (and other cited patents) as references, Appellants submitted a Section 1.131 Affidavit in connection with Appellants' amendment mailed on February 4, 1992 (the "February" Affidavit). A copy of the February Affidavit is annexed hereto as Appendix B.

The February Affidavit establishes that prior to the reference date, Appellants had prepared three species of the hydrolyzed food gums, guar gum, locust bean gum and tamarind seed gum, suitable for use as bulking agents in edible products. As demonstrated in Exhibits A and B to the February Affidavit, each of the hydrolyzed food gum species were characterized by the viscosity and polymer size limitations set

forth in Claims 29, 31 and 35. As demonstrated in Exhibit C to the February Affidavit, each species was successfully used as a bulking agent in food products. The February Affidavit establishes that these activities were carried out prior to the filing date of the Tomita patent. The Tomita patent is limited to the disclosure of a single species, Konnyaku polysaccharide (konjac gum), having modifications different from those claimed by Appellants. Two of the species described in Appellants' February Affidavit, guar gum and locust bean gum, are galactomannan gums (species closely related to konjac gum which is a glucomannan gum), which suggest the utility of other hexose backbone heteropolysaccharide food gum species in the claimed invention.

Thus, the February Affidavit establishes the anticipatory reduction to practice of three species of a genus (i.e., three species of depolymerized food gums selected from a generic group of seven species of gums, each having a DP 3 to 75 and a maximum viscosity with demonstrated, useful functional performance in foods). The claimed genus is thereby documented and the hydrolyzed polysaccharide disclosed in Tomita is suggested by the February Affidavit. By establishing the reduction to practice of a genus of hydrolyzed food gums which are functionally useful in foods as bulking agents, the February Affidavit antedates and removes the Tomita patent as a reference.

Notwithstanding the filing of the February Affidavit, the Examiner continued with the rejection over the Tomita reference, stating that the February Affidavit was inadequate to remove the reference, citing MPEP Section 715.03, and noting that the Affidavit does not disclose (a) a genus nor (b) all members of the Markush group, specifically the konjac gum taught by the Tomita reference.

In response to the Examiner's continuing rejection, Appellants submitted further arguments to distinguish the Tomita reference and submitted a second 37 CFR Section 1.131 Affidavit with an Amendment filed on September 20, 1993. The second Affidavit (the "September Affidavit") clearly establishes the reduction to practice of a genus which anticipates or suggests the konjac gum species disclosed in the Tomita patent.

The September 1.131 Affidavit includes an Invention Disclosure Statement document which expressly discloses the generic concept of "the use of the soluble heteropolysaccharide sources (e.g., guar, locust bean gum and tamarind gum) as the base material for the preparation of our bulking agent". The named species (guar, etc.) are expressly identified as examples of the genus, not limitations on the genus. The second Affidavit further discloses the concept of using the genus comprising water soluble hydrolysates of food gums, reciting "the invention described here overcomes the difficulties in utilizing gums as bulking agents. Enzymes are used to depolymerize the gums. With the shorter polymers and lower viscosities, the gums can be used at useful sucrose replacement levels, such as 15% of the weight (50% replacement of sucrose) of a typical yellow cake. The advantage of these products over current bulking agents is the balance between functionality and digestibility. No other bulking agent produced from natural heteropolysaccharides provides both of these benefits." Thus the genus was defined as "bulking agents

produced from natural heteropolysaccharides" having the advantage over the art of a "balance between functionality and digestibility." The claimed bulking agents are produced from "gums" which are "soluble" "natural heteropolysaccharides".

As for the Examiner's comment that the Section 1.131 Affidavit is inadequate because it does not disclose all members of the Markush group, specifically the konjac gum taught by the Tomita reference, the Examiner's comment is contrary to the law of the Court of Appeals for the Federal Circuit.¹ The sufficiency of the affidavit must be reviewed on the facts of each case. There is no single rule for a Markush group. Even if a Section 1.131 showing does not make out a prima facie case of invention of the entire chemical genus, so long as it (a) shows completion of the invention of the species disclosed in the Section 102 or 103 reference, or (b) shows completion of the invention of a species rendering obvious the species disclosed in the Section 103 reference, or (c) shows completion of a sufficient number and type of species to establish a generic invention encompassing the species disclosed but not claimed in the reference, then priority is established and the reference is removed. See In re Stempel, 113 USPQ 77 (CCPA 1957) and Ex parte Clark, 60 USPQ 72 (Bd. App., 1943), cited therein.

In Appellants' case, the konjac gum of the reference is a heteropolysaccharide comprising two monosaccharides (glucose and mannose). Thus it may be classified as a homolog or a very closely related species to the guar gum and locust bean gum of the first Affidavit which are heteropolysaccharides comprising two monosaccharides (galactose and mannose). Other, more distant species within Applicants' claimed genus include heteropolysaccharides comprising both monosaccharides and the acids of monosaccharides, together with other species of heteropolysaccharides which comprise substituted and unsubstituted sugar acids, and heteropolysaccharides which comprise three monosaccharides (e.g., tamarind seed gum which comprises glucose, xylose and galactose). The February Affidavit establishes a reduction to practice of three species of food gums within the claimed genus of seven species of gums at a date prior to the effective date of the reference. The September Affidavit establishes the generic concept of the claimed invention.

Thus, the 1.131 Affidavits submitted herein establish a generic invention which either (a) anticipates or (b) makes obvious the species disclosed in the Tomita reference. (See, footnote 6 and In re Shokal, Devlin and Winkler, 113 USPQ 283 (CCPA, 1957) at 285 which describes the number of species needed in an affidavit to establish reduction to practice of a generic invention ("...it seems evident therefrom that such number will vary depending upon the circumstances of particular cases. Thus, in the case of a small genus such as the halogens consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundred of species, a considerably larger number of reductions to practice would probably be necessary"). See also, footnote

¹ See, e.g., In re Schaub et al., 190 USPQ 324 (CCPA 1976); In re Stryker, 168 USPQ 372 (CCPA 1971); In re Clarke, 148 USPQ 665 (CCPA 1966); In re Hostettler, 148 USPQ 512 (CCPA 1966); and In re Stempel, 113 USPQ 77 (CCPA 1957).

6 and In re Schaub, et al., 190 USPQ 324, at 326 (CCPA, 1976), and In re Clarke, 148 USPQ 665, at 668-669 (CCPA 1966) which define closely related species within a genus having common properties for Section 1.131 affidavit purposes.)

4. Section 715.03 of the Manual of Patent Examining Procedure Incorrectly Cites the Law of the Court of Appeals for the Federal Circuit and Should be Held Inapplicable.

Assuming that the Examiner has correctly applied Section 715.03 of the MPEP in requiring that Appellants submit further evidence of the reduction to practice of konjac gum as a species of the edible formulations containing hydrolyzed food gums, then Appellants urge that the Board consider whether the MPEP correctly states the law of the Court of Appeals for the Federal Circuit ("CAFC") and whether Section 715.03 should be held inapplicable to patent prosecution.

In this regard, it is useful to turn to the language of 37 CFR Section 1.131², the language of Section 715.03 of the MPEP³ and the relevant language of the Court of Customs and Patent Appeals ("CCPA") decisions upon which the MPEP rule is based, so far as these authorities relate to the scope and sufficiency of the contents of the Affidavit in light of the disclosure of the reference.⁴

² Rule 1.131 provides: Affidavit or declaration of prior invention to overcome cited patent or publication.

(a) When any claim of an application or a patent under reexamination is rejected on reference to a domestic patent which substantially shows or describes but does not claim the same patentable invention, as defined in §1.601(n), as the rejected invention, or on reference to a foreign patent or to a printed publication, and the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the person qualified under §1.42, 1.43 or 1.47, shall make oath or declaration as to facts showing a completion of the invention in this country before the filing date of the application on which the domestic patent issued, or before the date of the foreign patent, or before the date of the printed publication, then the patent or publication cited shall not bar the grant of a patent to the inventor or the confirmation of the patentability of the claims of the patent, unless the date of such patent or printed publication is more than one year prior to the date on which the inventor's or patent owner's application was filed in this country.

(b) The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from the prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration of their absence satisfactorily explained. 37 CFR Section 1.131 1988).

³ Section 715.03 of the Manual of Patent Examining Procedure provides:

"In chemical cases, where generic claims have been rejected on a reference which discloses a species not antedated by the affidavit or declaration, the rejection will not ordinarily be withdrawn unless the applicant is able to establish that he or she was in possession of the generic invention prior to the effective date of the reference. In other words, the affidavit or declaration under >37 CFR<* 1.131 must show as much as the minimum disclosure required by a patent specification to furnish support for a generic claim.

The principle is well established in chemical cases, and in cases involving compositions of matter, that the disclosure of a species in a cited reference is sufficient to prevent a later applicant from obtaining a "generic claim." In re Steenbock, 1936 C.D. 594, 473 O.G. 495.

Where the only pertinent disclosure in the reference is a single species, which species is antedated by the affidavit or declaration, the reference is overcome. In re Stempel, 1957 C.D. 200, 717 O.G. 886.

MARKUSH TYPE CLAIM

Where a claim reciting a Markush group is rejected on a reference disclosing but not claiming a specific member of the group, the reference cannot be avoided by an affidavit or declaration under >37 CFR<* 1.131 showing members of the group."

M.P.E.P., Section 715.03, Revision 14, November 1992, page 700-81.

⁴ The relevant CCPA decisions begin with the decision of the Court in In re Steenbock, 30 USPQ 45 (CCPA) 1936. The patent application of In re Steenbock, 30 USPQ 45 (CCPA 1936), was finally refused by the Examiner on the basis of two publications which were statutory bars, having been published two years prior to the filing date of the application. The Steenbock invention involved a process for treating fungus with light comprising ultraviolet rays. The references disclose the processes of treating yeast (a species of fungus) by the same process. The Applicant had provided an affidavit swearing behind the published references and establishing that the Applicant had successfully subjected yeast to the process of the invention.

On the basis of this affidavit, the Board of Appeals reversed the decision of the Examiner and allowed the Applicants' claims to the process for treating yeast. The Board of Appeals affirmed the rejection of Applicant's claims to the process for treating fungus. Thus, the only claims remaining before the CCPA were the claims directed broadly to treatment of fungus.

The affidavit of the applicant was silent with respect to treatment of fungus. The application was amended during prosecution to state that yeast is an example of fungus, but as originally filed, the application made no reference to use of the process in connection with any fungus.

The Court of Customs and Patent Appeals held that:

The principle is well established in chemical cases, and in cases involving compositions of matter, that the disclosure of a species in a cited reference is sufficient to prevent a later applicant from obtaining generic claims, although the disclosure in an application of the species may not be a sufficient basis for a generic claim. (Citations omitted)

Id., at 46

The Steenbock holding should be limited on its facts to cases wherein neither the application, nor the affidavit, discloses the chemical genus which is the subject of claims at issue. The Steenbock affidavit was limited to a single species, which species was disclosed in the reference. The Steenbock claims were generic, not Markush group claims, first presented in a continuing application and absent from the parent application. No evidence of a prior generic invention was given by the Applicant. Finally, the decision of the CCPA was influenced by the fact that the Applicant attempted to obtain a earlier date for his generic claim by stating that the pending claims were divisional claims, when in fact they were a continuation-in-part of the original disclosure. Thus, the scope of the affidavit was a secondary issue in the decision.

The next key decision involving the scope of Section 1.131 affidavits (formally Rule 75 affidavits) was In re Stempel, 113 USPQ 77 (CCPA 1957). The Applicant made a broad generic claim to certain Isopropenyl benzenes and to certain species within the scope of the broad claim. The claims were rejected over a reference patent disclosing, but not claiming, 3,4-dichloro-isopropenyl benzene, the subject matter of an allowed claim to one of the species of the invention.

The Applicant had submitted several affidavits establishing that the compound described in the allowed claim (and in the reference) had been prepared prior to the filing date of the reference. Based on this affidavit, the Board of Appeals reversed the Examiner with respect to the species claim.

The Board sustained the Examiner's rejection of the broad claim to Isopropenyl benzenes based on the reference disclosing a species of the claimed genus (isopropenyl benzenes).

The CCPA defined the issue as "when a domestic patent discloses only a single species of an invention and the applicant submits an affidavit under Rule 131 showing completion of the invention of that species prior to the effective date of the reference (which does not claim it), can that reference be used as the basis of the rejection of generic claims in the application?"

Id., page 79

In its decision, the CCPA cited Ex Parte Burt, 89 USPQ 186 (Bd. App., 1950) which held that an applicant need not show the invention as claimed being reduced to practice prior to the date of the reference, but must present an affidavit showing merely that as much of the claimed invention as taught in the reference had been reduced to practice prior to the date of the reference.

The Court held that the Board of Appeals had made a practice of misapplying the decision of In re Steenbock for the proposition that the affidavit must contain a generic disclosure to support a generic claim, notwithstanding the fact that the reference disclosing one species had been removed by an affidavit disclosing the same species. The In re Stempel Court observed that the Steenbock affidavit had nothing to do with the broad generic claims on appeal. The broad generic claims on appeal were rejected because there was no supporting disclosure in any of the earlier applications for the claims and the references amounted to statutory bars. The In re Stempel Court concluded that this misapplication of its earlier decision had led the board to conclude erroneously that a Rule 131 affidavit had to show as much as the minimum required in a patent specification to support a generic claim, without regard for the actual subject matter disclosed in the reference being removed.

The In re Stempel Court notes, with approval, the decision of the Board of Appeals in Ex parte Clark, 60 USPQ 72, 73 (Bd. App., 1943). In Ex parte Clark, the Board of Appeals reversed the Examiner's rejection of a generic (Markush) claim on the basis of a reference disclosing only one species. An affidavit had been submitted antedating the reference. The Board distinguished the In re Steenbock decision on the basis that

It is significant that the MPEP cites, and misapplies, the decision of *In re Steenbock* in requiring the affidavit to "show as much as the minimum disclosure required by a patent specification to furnish support for a generic claim." The evolution of the MPEP misapplication of *In re Steenbock*, may be traced to a similar treatment by the Board of Appeals which was identified by the CCPA in *In re Stempel*, 113 USPQ 77 (CCPA 1957).

The *In re Stempel* Court goes on to analyze the portion of 37 CFR Section 1.131, which provides "...the showing must show a reduction to practice of the claimed invention...." The Court differed with the Board of Appeals and held "we are convinced that under the law that all the applicant can be required to show is priority with respect to so much of the claimed invention as the reference happens to show. When he has done that he is disposed of the reference." *In re Stempel*, 113 USPQ 77, 81 (CCPA, 1957).

the generic Steenbock claims were refused because of lack of disclosure in the specification, not because of lack of showing in the affidavit.

The *In re Stempel* Court notes, with approval, several decisions of the Board of Appeals involving fact situations different from the facts of *In re Stempel*. These Board of Appeals decisions were characterized by the Court in the following manner:

In Ex parte Fryling the affidavits under Rule 131 showed, first, a prior reduction to practice of one species disclosed by the reference and, second, a conception, prior to the effective date of the reference, of a second species, coupled by diligence with a later reduction to practice, which established priority as to the second species also. The Board *allowed* the generic claims, finding that the affidavits showed completion of a generic invention prior to the effective date of the reference.

In Ex parte Pritchard the applicant attempted to swear back of a reference by showing reduction to practice of "a particular species." He was allowed a claim to that species. But on the appeal he was asking for broader claims, the subject matter of which the Board held to be *substantially shown in the reference*. Thus all pertinent subject matter in the reference had not been antedated and it was still a good reference against the broad claims.

In Ex parte Young an affidavit was accepted as establishing prior invention of a "particular species" but was held not to establish *priority* as to claimed generic subject matter. It is impossible to tell from the opinion how much pertinent disclosure the reference contained other than that which was covered by the showing of the affidavit, but it is obvious that it was considerable. That being so, *there was still anticipatory matter in the reference, not antedated*, by reason of which it could remain a good reference.

The decisions reached on the facts presented in these three Board decisions relied on in this case are, therefore, not, on the basis of their facts, precedents for the decision of the Board in this case....

An earlier Board decision than those considered above which is in accord with our view is Ex parte Clark, 60 USPQ 72, 73, (Bd. App. 1943), cited by neither party, wherein, as here, an examiner held a Rule 75 affidavit inadequate to overcome rejection of a generic (Markush) claim on a reference disclosing only one species which the affidavit had antedated, citing *In re Steenbock*, supra. In reversing, the Board said, "it was only necessary for applicant to overcome the *disclosure* of that patent to *eliminate* it as a reference." (Emphasis ours.) It correctly distinguished *In re Steenbock* on the ground that the refusal of generic claims in that case was "For lack of disclosure in the specification rather than lack of showing in the affidavit under Rule 75." To the same effect is Ex parte Clifford, 34 USPQ 232, (Bd. App. 1936, prior to *In re Steenbock*); see especially the concurring opinion of Thurber, Examiner in Chief, whose dissenting opinion in Ex parte Sebrell, 36 USPQ 80 (Bd. App. 1937), may have contributed to the schism which has developed in the Board. In this dissent he pointed out that when a reference has a generic disclosure, then the affidavit to overcome it should show prior completion of the generic invention to support a generic claim.

Id., at pages 79-80.

Thus, the In re Stempel Court held that the adequacy of a Section 1.131 affidavit should be reviewed on the basis of the facts of each case, including the extent of the disclosure of the specification as filed, the extent of the disclosure of the reference, the existence and nature of generic and species claims, and other factors affecting patentability of the claims in issue.

It seems that the MPEP Section 715.03 language applying the decisions of the CCPA is far more restrictive than the actual holding of the cases. Furthermore, the statement of Section 715.03 that "In other words, the affidavit or declaration under 37 CFR 1.131 must show as much as the minimum disclosure required by a patent specification to furnish support for a generic claim" is directly contrary to the holding of the CCPA in In re Stempel. Other CCPA decisions do not alter the In re Stempel holding.⁵

Among the CCPA decisions addressing the sufficiency of affidavits in removing alleged Section 102 references are three decisions of the CCPA concerning whether an affidavit showing an invention of the species and the conception of a genus comprising the species are sufficient to antedate indirectly a reference disclosing a different species within the claimed genus. These decisions include In re Schaub, Bernady, and Weiss, 190 USPQ 324 (CCPA, 1976); In re Clarke, 148 USPQ 665 (CCPA, 1966); and In re Shokal, Devlin, and Winkler, 113 USPQ 283 (CCPA, 1957). These decisions are in fundamental agreement on the basic concept that a single species can rarely if ever afford sufficient support for a generic claim. However, judicial precedent has not established any definite number of species which will establish completion of a generic invention and indirect antedating of a reference is expressly permitted in a proper case.⁶

⁵ The decisions discussed in footnote 4 are, or appear to be, concerned with Section 102 references. The CCPA addressed the problem of sufficiency of Section 1.131 affidavits in removing a Section 103 reference in In re Tanczyn, 146 USPQ 298 (CCPA 1965). The Tanczyn invention did not involve a genus-species relationship. The invention was directed to a metal alloy, containing a unique combination of nitrogen and molybdenum. In the Section 103 rejection, one reference was cited as disclosing a similar stainless-steel alloy containing nitrogen; the other reference disclosed a stainless-steel alloy containing molybdenum. An affidavit was submitted establishing that a nitrogen containing stainless-steel alloy had been prepared by the Applicants prior to the date of the reference.

The CCPA distinguished the facts of Tanczyn from the facts of Stempel, stating that Tanczyn was never in possession of a part of his invention until he had prepared a stainless-steel alloy containing both nitrogen and molybdenum. The alloy containing only nitrogen was outside of the claimed invention. In contrast, Stempel had established that one species of the invention had been successfully completed prior to the date of the reference. The CCPA specifically noted that the difference between Tanczyn and Stempel have quite a bit to do with the difference between any Section 102 novelty rejection and a Section 103 obviousness rejection, in that a Section 103 reference need not show the invention as claimed, while a Section 102 reference must show the invention as claimed. Thus, an affidavit which establishes the prior reduction to practice of the disclosure of a Section 103 reference does not necessarily establish the reduction to practice of the claimed invention, or a species exemplifying the invention.

⁶ In In re Shokal, the Court held "...it seems evident therefrom that such number will vary depending upon the circumstances of particular cases. Thus, in the case of a small genus such as the halogens consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably large number of reductions to practice would probably be necessary." In re Shokal, Devlin, and Winkler, 113 USPQ 283, 285 (CCPA, 1957).

In the case of the Shokal, et al. invention, the genus was defined as being limited to neutral compounds which are free of elements other than carbon, hydrogen and oxygen. The court found that neither the affidavit nor the patent application disclosed these generic properties as essential or desirable

in the claimed compounds. Disclosure in an earlier, related application which was broader than the claimed genus was claimed insufficient. The prior broad disclosure included compounds which were specifically excluded from the generic claims at issue.

In the case of the Clarke Invention, the applicant filed two affidavits, one establishing reduction to practice of several species of the claimed genus, and the second affidavit alleging, without any documentary evidence, the conception of the generic invention. The court confirmed "that appellant may, by a proper showing, overcome a reference which discloses a species within the generic claim, although he may not be able to show completion of that species prior to the effective date of that reference, where the reference is not a statutory time bar. Thus, indirect antedating of a reference is permitted in a proper case and the solicitor's view is contrary to existing law. However, we do not find, on the facts of this case, that appellant has established prior inventorship of so much of the invention, as defined in claims 1 and 2, as is necessary to antedate indirectly the species of the reference." *In re Clarke*, 148 USPQ, 665, 668-669 (CCPA, 1966).

The *In re Clarke* Court held:

It follows from the above views that antedating affidavits must contain facts showing a completion of "the invention" commensurate with the extent the invention is shown in the reference, whether or not it be a showing of the identical disclosure of the reference. In our view, where it can be concluded that facts, offered in a Rule 131 affidavit in support of a general allegation of conception and reduction to practice of the invention, would persuade one of ordinary skill in the art to a reasonable certainty that the applicant possessed so much of the invention as to encompass the reference disclosure, then that showing should be accepted as establishing prima facie a case of inventorship prior to the reference, sufficient for the purpose of overcoming the reference in an ex parte case. See *In re Shokal*, supra, 44 CCPA at 859, 113 USPQ at 286. Upon satisfying that test, species of the reference falling within the claim may be antedated indirectly. On a review of all the evidence presented here, we conclude that appellant has not established that to be the case.

Here, the isopropyl species of Stetter which must be antedated is the first member of a structurally homologous series in which R in the structure depicted above is a branched-chain alkyl radical. The first affidavit of appellant shows both the preparation of the methyl compound, the first member of the alkyl series, and a determination that the methyl compound has diuretic activity. While other members of the alkyl series, or even the branched-chain alkyl series, might be said to be structurally evident or prima facie obvious to one skilled in the art upon preparation of the methyl species, the evidence is *inadequate* to show that appellant considered any other members of those series to be part of the invention. The fact that the species shown in the affidavit are members of an homologous series, e.g. alkyl, is not necessarily conclusive that alkyl is of such significance that another member of the series is part of the invention.

Further, there is no evidence here that one of ordinary skill in the art would have considered, or that appellant himself considered that the isopropyl species reasonably could be expected to have properties⁶ related to that found for the methyl species, such that the isopropyl species would be properly included within the invention. We fail to find facts showing appellant had any appreciation that the invention was of such scope as to include or point to the isopropyl species of Stetter.⁷ The requirement is for facts and not conclusions alone, *In re Garratt*, supra.

Although a phenyl species is also shown in the first affidavit, appellant's position is not strengthened thereby. There is no evidence that, prior to the effective date of Stetter, appellant determined that the phenyl species was part of the invention. In our view, the affidavit showing with respect to phenyl is little related to that portion of the genus, the alkyl and branched-chain alkyl series, within which lies the isopropyl species of Stetter. We recognize that a showing with respect to another type or substituent within the genus claim, though not within the alkyl or branched-chain alkyl series thereof, could be relevant on the question of antedating the isopropyl species of the reference. Where it could be shown that such a diverse substituent as phenyl was then known to have properties related to those of the methyl species, it would indicate that the invention is relatively independent of the nature of the R substituent. That being so, a compound structurally further removed could be effective to antedate the compound of the reference. Thus, an R substituent even more diverse than methyl might serve to antedate isopropyl where it is also shown that the structure of the R substituent is of relatively little effect in the compound as a whole. However, the affidavit does not show the phenyl species to have properties similar to methyl, and hence there is no evidence of such independence in the record. We must conclude that the showing only of the making of the phenyl species is of little probative value on the issue of whether the isopropyl species is antedated.⁸

None of the CCPA's Rule 1.131 affidavit decisions have been reversed or significantly modified by the Court of Appeals for the Federal Circuit ("CAFC").⁷

Returning to the language of Section 715.03 of the MPEP, the first sentence: "In chemical cases, where generic claims have been rejected on a reference which discloses a species not antedated by the affidavit or declaration, the rejection will not ordinarily be withdrawn unless the applicant is able to establish that he or she was in possession of the generic invention prior to the effective date of the reference"

*We mean simply the common property or properties possessed by all the species which qualify them for inclusion in a genus. It is the common property or properties which define and delimit the genus.

⁷It is clear that if appellant's proofs were satisfactory here to establish the genus of claim 2, he would carry claim 1 as well.

*What is pointed out here about the relevancy of showings with regard to the phenyl species may be true of the showings with regard to the ethylene bridge species (Stetter's Compound XI), shown and tested and found to have antiviral activity in the first affidavit, but apparently only relevant on the factor of relative independence because the bridge compound is outside the claimed genus.

On the facts before us we are not convinced that the showings in the affidavits are adequate to antedate indirectly Compound VII of Stetter. We cannot say that it is reasonable to conclude from the affidavit showings that so much of the invention as encompasses the reference species was in appellant's possession, and thereby reduced to practice prior to the effective date of the reference.

Id., at 670-671.

Under similar, but distinguishable facts, the CCPA held an affidavit sufficient in *In re Schaub, Bernady and Weiss*, 190 USPQ 324 (CCPA, 1976). Unlike the Clarke case, the Schaub case involved affidavit evidence establishing the reduction to practice of two adjacent homologs species which bracketed the reference species. The applicants contended and the court accepted that the reduction to practice of the two species bracketing the reference species gave rise to a presumption of obviousness. In other words, the species described in the reference would have been obvious to one of ordinary skill in the art in view of the species reduced to practice by the applicants prior to the effective date of the reference. The court held that such a reference may be indirectly antedated and that it is not necessary to establish that the applicants had the generic invention in their possession prior to the effective date of the reference. This was held unnecessary because it was otherwise established by affidavit that the facts existed to persuade one of ordinary skill in the art to a reasonable degree of certainty that the applicants possessed so much of the invention as to encompass the reference disclosure. Id., at 326. The Court went on to reverse the decision of the Board of Appeals, stating that the affidavit was effective to antedate the reference and that the claims were allowable. See also, *In re Hostettler*, 148 USPQ 514 (CCPA, 1966) (affidavit disclosing part of generic invention held adequate and affidavit requirement held not to be coextensive with 35 USC Section 112 requirement).

⁷ In a case where the affidavit failed to establish diligence by the inventor from conception one month prior to the publication date of the earliest Section 103 reference to the inventor's "reduction to practice" seven months later, the lower court found the affidavit inadequate to antedate the references, and the CAFC agreed. *Greenwood v. Hattori Seiko Co.*, 14 USPQ 2d 1474 (CAFC, 1990), affirming in part, *Greenwood v. Seiko Instruments & Electronics, Ltd.*, 13 USPQ 2d 1245 (D. Ct. D.C., 1989). This case did not involve a Section 102(e)/103 rejection (i.e., a pending patent application unknown to inventor during reduction to practice), but a Section 102(a)/103 rejection (i.e., a publication presumably known to the inventor during reduction to practice).

Several other CAFC decisions clarify the distinction between Section 102(g) references which cannot be removed by a Section 1.131 affidavit and must be resolved in an interference, and Section 102(e) references. A Section 102(e) reference discloses, but does not claim the subsequently claimed invention and may be removed by a Section 1.131 affidavit. See, e.g., *In re Zletz*, 13 USPQ 2d 1320 (CAFC, 1989); and *In re Mulder* 219 USPQ 189, 193 (CAFC, 1983) (a 102(a) reference should not be treated as a 102(g) patent with respect to affidavit evidence of diligence in reduction to practice).

Similar cases have arisen in obviousness double-patenting situations. See, e.g., *Quad Environmental Technologies v. Union Sanitary District*, 20 USPQ 2d 1392 (CAFC, 1991).

accurately reflects the law defined by the CCPA. The second sentence: "In other words, the affidavit or declaration under 37 CFR 1.131 must show as much as the minimum disclosure required by a patent specification to furnish support for a generic claim" is clearly contrary to the law of the CCPA (and CAFC) with respect to Section 103 references. The second sentence provides a more narrow view of the sufficiency of a Section 1.131 affidavit than the CCPA decisions regarding Section 102 references. For either 102 or 103 references, the CCPA has held the affidavit must be merely sufficient to remove the reference. The CCPA never held the affidavit had to establish reduction to practice of the complete, claimed invention as required by 35 USC Section 112. The CCPA held the affidavit requirement is not coextensive with Section 112.

The third sentence of Section 715.03 of the MPEP ("The principle is well established in chemical cases, and in cases involving compositions of matter, that the disclosure of a species in a cited reference is sufficient to prevent a later applicant from obtaining a "generic claim".) is contrary to the law defined by the CCPA. See, e.g., *In re Ruff*, 118 USPQ 340 (CCPA 1958). The CCPA holdings are more accurately reflected in MPEP Section 715.02, irrespective of whether the invention is a chemical one.

Turning to the facts of Appellants' case, the CCPA holdings support the scope and sufficiency of the affidavits in removing the Tomita reference. It can be seen that the February Affidavit establishes the reduction to practice of the tamarind seed gum, locust bean gum and guar gum with the claimed structural and functional limitations. These facts may be viewed as evidence of the reduction to practice of three species which (as in *In re Schaub, et al.*, *supra*) render obvious the species disclosed in the Tomita reference. The Tomita species is konjac gum. Konjac gum is a heteropolysaccharide comprising two monosaccharides, mannose and glucose. Guar gum is a homolog of konjac gum, a heteropolysaccharide comprising two monosaccharides, galactose and mannose. Locust bean gum is a structural isomer of guar gum which also comprises two monosaccharides, galactose and mannose. The entire genus claimed by applicants consists of only seven species and combinations thereof. Furthermore, the generic invention is described in the document attached to the September Affidavit.

For these reasons, Section 715.03 of the MPEP should not be applied to Appellants' affidavits.

5. **Claims 29-35 Are Patentable Under 35 USC Section 103 Over The Hill Patent, In View of the Barnett European Patent Publication.**

Appellants' claims are directed to edible products comprising hydrolyzed food gums have the following, limiting characteristics:

- Edible
- Water Soluble
- Hydrolyzed food gums selected from the group consisting of guar gum, locust bean gum, konjac gum, xanthan gum, pectin, carrageenan and alginates

Weight average molecular weight of 500 to 50,000
Average DP of 3 to 75
Maximum viscosity of 50 cps in a 30% solution
Functional as bulking agents; and

Are used as sugar replacers.

In contrast, the Hill reference discloses guar gum which is treated to remove its "snot-like" character and, at the same time, to provide a sterilized gum having benefits in commercial use (column 9, lines 1-13). In Example 11, columns 19 and 20 of Hill, it is disclosed that the viscosity of the guar gum is "not greatly reduced" by the depolymerization treatment. Further evidence of the high viscosity of the Hill guar gum product is provided in Examples 1 and 2, columns 11 and 12 of the Hill reference. A 10 percent starch solution gives a viscosity from 12,550 to 105,000 cps after depolymerization treatment. Hill's depolymerization treatment is limited to an acid treatment employing certain sulfonic acids in the presence of non-porous particles of silica coated with a surfactant. Hill does not suggest Appellants' invention.

The Barnett reference discloses water soluble bulking agents comprising modified and unmodified hemicelluloses. Hemicelluloses are not heteropolysaccharides. The Barnett bulking agents are prepared from nonwoody, lignocellulosic substrates such as corn bran, alfalfa, hay, and the like. These materials all have pentose, not hexose, polymer backbones. Thus, Appellants' invention is not suggested by the Barnett reference.

As for the Section 103 rejection, neither of the references, either alone or taken together, suggest Appellants' invention. Appellants' selection of a hexose backbone polymer for depolymerization provides the limited scope of food gums which may be used as a substrate for production of the heteropolysaccharide bulking agent. The food gums substrate is desirable because food gums have a proven record of safety in foods for human consumption and provide functional characteristics in the depolymerized form which have beneficial properties. For example, the grittiness and residual mouthfeel of the cellulosic and hemicellulosic bulking agents are undesirable. These properties are absent from the bulking agents derived from food gums. Furthermore, Appellants' invention is limited to edible products comprising heteropolysaccharides having a DP of 3 to 75 because these materials are substantially non-digestible. (See Claims 29, 30, 33 and 35.) In contrast, mono- or disaccharides or food grade homopolysaccharides such as starch, glucan and some celluloses, upon depolymerization, are substantially digestible and provide caloric content to foods.

As can be seen in Appellants' data presented in Table III and Table IV and Example 12, pages 24-28, the molecular size and weight of the bulking agents and the amount of depolymerization are critical limitations to the utility of the bulking agents as functional replacements for sugar in foods. (See Claims 31-32 and 34.) For example, Table III shows that depolymerized guar gum having a viscosity in a 30 percent solution of 2,500 cps yields a cake with unacceptable quality. The same guar gum sample also contained 15.9 percent, by weight, of fragments having a weight average molecular weight of more than 10,000.

Similar results are shown for depolymerized guar gum used to make puddings. None of the references disclose this relationship between molecular size and weight distribution and functionality of the bulking agent.

The same comment applies to the selection of substrates for depolymerization. Appellants' selection of certain food gums for their functional characteristics is not suggested by disclosures in the art. For example, as noted earlier, Hill teaches a light depolymerization process so as to improve the functional characteristics of the food gums as gums. Hill does not suggest the use of depolymerized gums as bulking agents.

Neither the Hill nor the Barnett reference contains a suggestion that the optional depolymerization treatment level of Barnett would be useful to treat the guar gum used by Hill. In fact, Barnett's implied teaching is that the degree of conversion (depolymerization) of hemicellulose is not critical to the use of Barnett's claimed group (the claimed group contains materials which are highly converted or not converted at all) of hemicellulose materials useful as food bulking agents. See Claim 1 of Barnett. The teachings of Barnett would not lead one to further convert Hill's guar gum so that it may be used as a bulking agent in food. Instead, the Barnett teaching would suggest that depolymerization, molecular weight and the resultant viscosity changes are not critical to the use of bulking agent in foods. Of course, Barnett is silent on the topic of depolymerized guar gum and, therefore, suggests nothing which would cause one to combine its teachings with those of Hill. See, Uniroyal v. Rudkin-Wiley, 5 USPQ 2d 1434 (CAFC 1988) (something in the prior art as a whole must suggest the desirability and, therefore, the obviousness of combining particular pieces of art). Hill and Barnett contain no suggestion to combine a particular viscosity characteristic, or combine a particular degree of polymerization or to combine a particular molecular weight range of the hemicellulosic materials of Barnett with a non-cellulosic heteropolysaccharide such as guar gum, for use as a bulking agent in edible products.

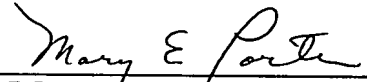
In fact, as shown in the data produced by Appellants on page 25, lines 15-32, the degree of polymerization and the resultant viscosity characteristics of the bulking agents are critical to the efficacy of the bulking agents in edible products when used as a functional substitute for sucrose and other caloric ingredients.

CONCLUSION

Should the Board conclude that a Section 1.131 affidavit is needed to remove the Tomita reference and that MPEP Section 713.03 has been properly applied, then Appellants respectfully request that MPEP Section 715.03 be held inapplicable to Appellants' application in view of conflicting CAFC law.

Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the Examiner's Section 102(e) and 103 rejections and allow Claims 29-35.

Respectfully submitted,



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National Starch and Chemical Company
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December 16, 1993

APPENDIX A

APPENDIX A

29. An edible formulation, comprising edible, water soluble hydrolysates of food gums selected from the group consisting of guar gum, locust bean gum, konjac gum, xanthan gum, pectin, carrageenan, and alginates, and combinations thereof, wherein the hydrolysates of food gums have a weight average molecular weight of 500 to 50,000 and an average DP of 3 to 75, and wherein the hydrolysates of food gums function as bulking agents in the edible formulation.

30. The edible formulation of Claim 29, wherein the hydrolysates of food gums are substantially non-digestible.

31. A sweetened edible formulation, comprising a sweetener having fewer calories than sucrose and a substantially non-digestible depolymerized food gum selected from the group consisting of guar gum, locust bean gum, konjac gum, xanthan gum, pectin, carrageenan, and alginates, and combinations thereof, wherein the depolymerized food gum has an average DP of 3 to 75.

32. The sweetened edible formulation of Claim 31, further comprising aspartame, or its salts or metal complexes, acesulfame-K, alitame, trichlorogalactosucrose, cyclamates, saccharin, fructose, neohesperidine, or mixtures thereof.

33. The edible formulation of Claim 29, wherein the edible formulation is selected from the group consisting of baked goods; puddings, creams and custards; jams and jellies; confections; soft drinks and other sweetened beverages, in liquid or dry form; sauces and salad dressings; ice cream and frozen desserts; and pharmaceuticals.

34. The edible formulation of Claim 33, wherein the formulation further comprises aspartame, or its salts or metal complexes, acesulfame-K, alitame, trichlorogalactosucrose, cyclamates, saccharin, fructose, neohesperidine, or a mixture thereof.

35. A method for providing non-nutritive bulk to edible products, comprising the steps:

- a. depolymerizing a food gum selected from the group consisting of guar gum, locust bean gum, konjac gum, xanthan gum, pectin, carrageenan, and alginates, and combinations thereof, to form a water soluble, substantially non-digestible, bulking agent, having an average DP of 3 to 75; and
- b. substituting the depolymerized food gum for 0.5 to 100% of at least one nutritive component of the edible product,

wherein the depolymerized food gum provides the physical, organoleptic and non-sweetening, functional benefits of the nutritive component for which the depolymerized food gum was substituted.

APPENDIX B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	:	
Chiu, et al.	:	
Serial No. 07/525,943	:	Group Art Unit: 132
Filed: May 17, 1990	:	Examiner: Joseph Gollan
For: BULKING AGENTS AND PROCESSES FOR	:	
PREPARING THEM FROM FOOD GUMS	:	

Commissioner of Patents and Trademarks
Washington, D. C. 20231

Sir:

AFFIDAVIT UNDER 37 C.F.R. SECTION 1.131

State of New Jersey)
) ss
County of Somerset)

We, Dr. Chung-Wai Chui, Matthew J. Henley and James P. Zallie, being duly sworn, dispose and say that:

1. We are named inventors of the above-captioned patent application and inventors of the subject matter described and claimed in Claims 29-35 therein. We have reviewed the Office Action, dated September 9, 1991, in the above-captioned patent application.

2. We make this affidavit to antedate the references: U.S. Patent No. 4,971,814, filed December 29, 1989 and issued November 20, 1990 to Tomita, et al.; European Patent Application Publication No. 0,359,075, published March 21, 1990 by Schnepf, et al.; and International Application Published Under the Patent Cooperation Treaty, Publication No. WO 91/11112, published August 8, 1991, by Whistler, claiming a U.S. priority filing of January 24, 1990, under U.S. Serial No. 469,153, which have been brought to the Examiner's attention in the above-captioned application.

3. Prior to December 29, 1989, we had completed our invention as described and claimed in the subject application in this country, as evidenced by the following:

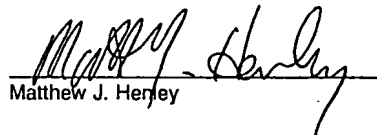
a. Prior to December 29, 1989, under the direction of Matthew J. Henley, a technician, Dana Janik, prepared depolymerized food gums having a DP of about 3 to 75, as evidenced by the copy of Laboratory Notebook Page Nos. 134 and 137 of Laboratory Notebook No. 6231, which pages are attached hereto as Exhibit A. Under the direction of Matthew J. Henley, the depolymerized food gums were subsequently tested for reducing sugar content, viscosity in solution and molecular weight as evidenced by the copy of Laboratory Notebook Page No. 8 of Laboratory Notebook No. 6698 and the copy of a two page

summary of gel permeation chromatography test results which pages are attached hereto as Exhibit B.

b. Prior to December 29, 1989, under the direction of James P. Zallie, a chemist, Paul Vjada, prepared cakes containing depolymerized food gums (tamarind, guar gum and locust bean gum) having a DP of about 3 to 75 as a bulking agent in lieu of part of the sucrose normally contained in the cakes, and tested the functional and organoleptic qualities of the cakes, as evidenced by the copy of Laboratory Notebook Page No. 25 of Laboratory Notebook No. 6616, which page is attached hereto as Exhibit C.

4. Each of the dates have been purposely deleted from Exhibits A, B and C.


Dr. Chung-Wai Chiu


Matthew J. Henley

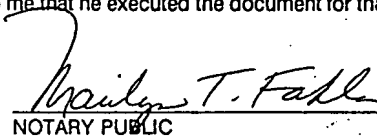

James P. Zallie

National Starch and Chemical Company
P. O. Box 6500
Bridgewater, New Jersey 08807

February 4, 1992

Country:	United States of America)	
)	
State:	New Jersey)	ss:
)	
County:	Middlesex)	

On this 4th day of February, 1992, before me personally appeared Dr. Chung-Wai Chiu, Matthew J. Henley and James P. Zallie, to me known and known to me to be the person mentioned in and who executed the foregoing document; and he duly acknowledged to me that he executed the document for the uses and purposes therein set forth.


NOTARY PUBLIC

MARILYN T. FAKLA
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires July 18, 1993

EXHIBIT A

134

Page No.

NATIONAL STARCH

Project No.

612.2/1295Xff

Date Started

Object

Preparation of enzyme degraded Guar
and Locust Bean Gum

Guar Gum

2 kg of Guar Gum

Solids $\approx 20\%$ Sodium Benzoate $\rightarrow 0.1\%$ for solutionpH ≈ 4 $T = 70^\circ\text{C}$

Gummosse enzyme

Locust Bean Gum

2 kg of Locust Bean Gum

Solids $\approx 20\%$ Sodium Benzoate $\rightarrow 0.1\%$ for solutionpH ≈ 4 $T = 70^\circ\text{C}$

Gummosse enzyme

Procedure: 0.1% Sodium Benzoate dissolved in destd. H_2O pH ≈ 4 , kept
 70-75°C and stirred 5 gallon jar in constant temp. water bath, 70°C
 then added 10 ml of gummosse enzyme. The 1st Guar Gum added 2 kg
 of Guar Gum slaked. 2nd Locust Bean Gum added 2 kg
 for second batch added 10 ml gummosse enzyme. 3rd Locust Bean Gum
 and then added 2 kg of Locust Bean Gum and recet till
 20-25% solids.

SAMPLE	Amount of enzyme	Rx Time	% PS.	SAMPLE	Amount of enzyme	Rx Time	% PS.
6231/134-1	10 ml 1 kg Gum	0 hr 20 hrs.	$\rightarrow 12\% \text{ PS}$	6231/134-2	10 ml 1 kg	1 hr	$\rightarrow 25\% \text{ PS}$
(Guar Gum)	added sol. enzyme	0/45	16% PS	Locust Bean Gum	added Locust Gum		
	7 ml 1 kg of gum	68 hrs					
	added 5 ml/kg gum	0/10	$\rightarrow 17\% \text{ PS}$				
		72	used 31 ml of 1% soln deactivated				

OBSERVATION:

These larger quantities
 were prepared to examine
 the functional properties of these materials in food systems.

WORK OF:

Law J. Smith

DATE:

I WITNESS THIS DOCUMENT AND UNDERSTAND ITS CONTENTS

Signature

Date

After witnessing, corrections or changes may
 never be made in the grid area, but may be
 noted at any time in this margin.

Project No.

6231.2/1412 FEF

Date Started

Object

Preparation of enzyme degraded Amarant (big batch)

Materials:

2 1/2 lb of Amarant gum

Solid \rightarrow 20%

Cellulase enzyme (about 25 ml / 1 lb gum)

pH \rightarrow 5 (6231:137-1)

Procedure:

300 g of Amarant gum (mer-bare)

0.1% Sodium Benzoate

Solid \rightarrow 20%pH \rightarrow 5.8°C

Cellulase enzyme (about 20 ml / 1 lb of gum)

Sample	Amount of enzyme used	Rx Time (hrs)	% RS
6231:137			
6231:137-1	25 ml of Cellulase enzyme / 1 lb of gum	20 hrs	\rightarrow 22% degraded by HPLC
6231:137-2	20 ml of Cellulase enzyme / 1 lb of gum	20 hrs	\rightarrow 23% degraded by HPLC

Observation: The big batch of Amarant 6231:137-1 will be submitted to Food Lab along with other and low-bare gum to examine the nutritional properties of these products (also evaluated in color and findings).

Diana Janti

M. Hurley

Signature

Date

After witnessing, corrections to changes may
never be made in the grid area but may be
made in the area below the grid.

WORK ON

I HEREBY CERTIFY THAT I HAVE READ AND UNDERSTAND THE CONTENTS

EXHIBIT B

Project No.

691.2/1412 FER

Date Started

Object

Evaluation of Bulking agents (Guar, Tamarind)
(Viscosity test)OBJECTIVE: IS TO COMPLETE THE PATENT DATA
EVALUATE THE BROOKFIELD VISCOSITY VS %RSProcedure: 30g of Guar, Locust Bean Gum or 50g of Tamarind
dispersed in 800 (30% sol; 50% sol) cooked to 20 min
fully cooled down to 72°F, checked viscosity by prod
(20 rpm; spindle #2)

SAMPLE	% RS	SOLIDS %	BROOKFIELD 72°F; 20 rpm	TYPE OF GUM
6231:151-1	10.0%	50.0%	900. cps	→ Tamarind
6231:101-2	15.0%		—	
6231:151-2	17.0%		300. cps	
6231:102	20.0%		260. cps	
6231:137	22.0%		240. cps	
6231:149	24.0%		150. cps	
6231:151-3	28.0%		140. cps	
6231:188	8.0%	30%	5.600 cps	→ GUAR
6231:116	10.0%		3.800 cps	
6231:85-1	15.0%		80. cps	
6231:84-1	20.0%		50. cps	
6231:87-2	33.0%		20. cps	
6231:85-2	23.0%		36. cps	→ Sunfiber
SUNFIBER	(~8%)	30%	1.700 cps	
6231:113	35%	30%	20. cps	→ Locust Bean Gum
6231:134-2	38%	30%	20. cps	
6698:15-1	9.0	30%	6.000 cps	
6698:16-1	10.4		2.100 cps	
6465:29-3	12.0		3.700 cps (not present)	

WORK OF:

Dave Jank

DATE:

WITNESS THIS DOCUMENT AND UNDERSTAND ITS CONTENTS

M. Jank

Signature

Date

10:14

=====

STATUS REPORT

LOG NUMBER : 900129500
SUBMITTER : M~~rs~~HENLEY
SAMPLE I.D. : 6231:137

CAG CONTACT :
CC RESULTS TO : CPI/THW/D JANIK/FILE
PROBLEM OR PROJECT : LOW BANK GPC REPORT MW AND % COMPOSITION OF MAJOR PEAKS
OF THIS DEGRADED TAMRIND SAMPLE
SAMPLE COMPOSITION : DEGRADED TAMARIND DE= 24

ANALYSIS	DESCRIPTION	SPECIFIC INFORMATION NEEDED
=====	=====	=====
GPC	GEL PERMEATION CHROMATOGRAPHY	MW AND COMPOSITION

TEST : GPC

ACTUAL ANALYST : HOLLEYWOOD
ACTUAL INSTRUMENT : WATERS 150C
REF. NOTEBOOK NUMBER : 6615-73
DATE COMPLETED :

COLUMN 2PLGEL MIXED + 2PLGEL 500, DMSO/0.03M NANO3, 0.7ML/MIN, DEXTRAN STD
~~SAMPLE~~ ~~PK1-MW(%)~~ ~~PK2MW(%)~~ ~~PK3MW(%)~~
6231-137 2758(11.4%) 1095(82.0%) 130(5.4%)

CHROMATOGRAM IS ATTACHED.
.
.
.



C.A.G.

=====

15:08

STATUS REPORT

LOG NUMBER : 900321200

SUBMITTER : D. JANIK

SAMPLE I.D. : 6698:16-1,6698:16-2,6231:134-1

CAG CONTACT :

CC RESULTS TO : CPI/THW/M.HENLEY/FILE

PROBLEM OR PROJECT : GPC OF SAMPLES (LOW BANK).REPORT MAJOR PEAKS MW AND
AREA %.

SAMPLE COMPOSITION : ENZYME DEGRADED GUAR GUM.

ANALYSIS	DESCRIPTION	SPECIFIC INFORMATION NEEDED
=====	=====	=====
GPC	GEL PERMEATION CHROMATOGRAPHY	LOW BANK

TEST : GPC

ACTUAL ANALYST : HOLLEYWOOD

ACTUAL INSTRUMENT : WATERS 150C

REF. NOTEBOOK NUMBER : 6615-84

DATE COMPLETED :

COLUMN 2 PLGEL MIXED + 2PLGEL 500, DMSO/0.03M NANO3, 0.7ML/MIN, CAL STD
DEXTRAN.

SAMPLE	PK1 MW(%)	PK2 MW(%)	PK3 MW(%)	PK4 MW(%)	PK5 MW(%)
6698-16-1	15,092(72.4)	1173(7.5)	422(8.4)	309(5.4)	211(2.9)
16-2	14,827(70.5)	1163(7.7)	425(8.1)	309(5.0)	210(3.0)
6231-134-1	4,950(72.5)	1122(14.2)	429(3.5)	313(4.0)	212(5.9)

CHROMATOGRAMS ARE ATTACHED.

EXHIBIT C

Project No.

Cakes

Date Started

Object

compare cakes made w/ M. Henley's
soluble fibers at 50 and 75% sucrose
replacement (vs. Polydextrose)

Flour — 125g
sugar — 73.5g
CRISTO — 47g
BP — 4.8g
H₂O — 148 mL

salt — 2.7g
vanilla — 2.6g
NFDM — 15g
WDE — 12.5g

50%

36.75g SUGAR
110.25g SAMPLE

75%

(Sampler)

Polydextrose

Tamarind (6231:137) 22% RS

Guar Gum (6231:134-1) 20% RS

LBG (6231:134-2) 38% RS

all used at 50% and 75% sucrose replacement.

(Tamarind)

most functional cake
flavor very heavy and burnt

(LBG)

functionality OK to undesirable
flavor bitter (offensive)

(Guar)

Least functional cake, but flavor
most desirable (like caramel)

Try GUAR in Addings

WORK OF

J. Vazda

DATE:

I WITNESS THIS DOCUMENT AND UNDERSTAND ITS CONTENTS

Signature

Date

APPENDIX C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	:	
	:	
Chiu, et al.	:	
	:	
Serial No.: 07/525,943	:	Group Art Unit: 1302
	:	
Filed: May 17, 1990	:	Examiner: J. Gollan
	:	
For: BULKING AGENTS AND PROCESSES FOR	:	
PREPARING THEM FROM FOOD GUMS	:	

SUPPLEMENTAL AFFIDAVIT UNDER 37 C.F.R. SECTION 1.131

State of New Jersey)
) SS:
 County of Somerset)

Commissioner of Patents and Trademarks
 Washington, D.C. 20231

Sir:

We, Dr. Chung-Wai Chiu, Matthew J. Henley and James P. Zallie, being duly sworn, depose and say that:

1. We are named inventors of the above-captioned patent application and inventors of the subject matter described and claimed in Claims 29-35 therein. We have reviewed the Office Action, dated April 17, 1992, in the above-captioned patent application.

2. We make this Affidavit to antedate U.S. Patent Nos. 4,971,814, filed December 29, 1989 and issued November 20, 1990 to Tomita, et al.; and 5,073,387, filed January 24, 1990 and issued December 17, 1991 to Whistler, which have been cited by the Examiner in the above-captioned application.

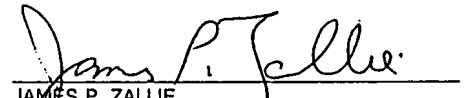
3. Prior to December 29, 1989, we had completed our invention as described and claimed in the above-captioned patent application in the United States, as evidenced by the following:

a. prior to December 29, 1989, we prepared the invention disclosure document that is annexed hereto as Exhibit A, which documents our invention of bulking agents prepared by enzymatically depolymerizing non-cellulosic or non-starch heteropolysaccharides to a degree that permits the polysaccharide to function like sucrose while retaining the low digestibility of the base.

4. Each of the dates, together with certain confidential information of National Starch and Chemical Company, have been purposely deleted from Exhibit A.


DR. CHUNG-WAI CHIU


MATTHEW J. HENLEY


JAMES P. ZALLIE

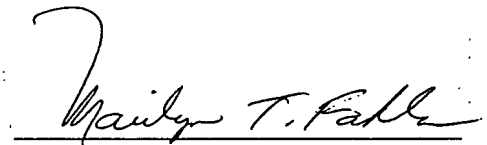
National Starch and Chemical Company
P.O. Box 6500
Bridgewater, New Jersey 08807

October 16, 1992

NOTARIAL CERTIFICATE

United States of America)
)
State of New Jersey) SS:
)
County of Middlesex)

On this ^{16th} day of October, 1992, before me personally appeared Dr. Chung-Wai Chiu, Matthew J. Henley and James P. Zallie, to me known and known to me to be the person mentioned in and who executed the foregoing document; and each duly acknowledged to me that he executed the document for the uses and purposes therein set forth.


Notary Public

MARILYN T. FAKLA
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires July 19, 1992

[illegible][illegible]

The information contained herein is confidential proprietary information of National Starch and Chemical Corporation and is to be maintained confidential and used solely for the benefit of National Starch and Chemical Corporation.

INVENTION DISCLOSURE

Type in Duplicate -- Send Original
and Copy to Patent Department, Bridgewater
Send Additional Copy to C. Iovine, Bridgewater

The following invention is submitted for patent consideration:

TITLE: LOW CALORIE BULKING AGENTS

1. SUMMARY OF IDEA: PURPOSE AND DESCRIPTION OF INVENTION:

This invention covers the production of bulking agents for the high level replacement of sucrose in food systems containing a high percentage of sucrose. The bulking agent products are low-caloric in nature and provide the functional properties of sucrose, excepting sweetness. They are prepared by enzymatically depolymerizing non-cellulosic or non-starch heteropolysaccharides to a degree that permits the polysaccharide to function like sucrose while retaining the low digestibility of the base.

continued page 2—

2. HOW DOES THIS DIFFER FROM, AND WHAT ARE ITS ADVANTAGES OVER WHAT HAS BEEN DONE BEFORE. EXACTLY WHAT PART OF THIS PRODUCT OR PROCESS IS NOVEL AND "UNEXPECTED"?

Our approach is to utilize readily available bases (e.g., guar and tamarind) that contain a high percentage of dietary fiber. Because of the low digestibility of dietary fiber, there has been much interest in using these as low calorie bulking agents. However, these bases in the unmodified state provide undesirable properties, such as increased water binding, viscosity, etc., that limit the useful usage levels; an example would be guar gum which is generally not used in levels higher than 2%.

continued page 2—

3. (a) HAVE YOU SEARCHED THE LITERATURE, INCLUDING PATENTS AND JOURNALS, MANUFACTURERS' BULLETINS OR OTHER AVAILABLE LITERATURE? *YES NO

WHAT TIME PERIOD DOES THE SEARCH COVER? 1971 - Present.

WHAT DATA BASE(S) WERE SEARCHED? CA / US World Patents.

(b) WHAT DID YOUR SEARCH REVEAL THAT MIGHT POSSIBLY BE CONSIDERED TO ANTICIPATE YOUR IDEA?

The literature search showed no indication of the use of enzymes to produce a bulking agent from heteropolysaccharides.

(c) THE PATENT OFFICE NOW PLACES AN OBLIGATION ON THE INVENTOR(S) TO CITE PERTINENT REFERENCES. WHAT DO YOU CONSIDER TO BE THE CLOSEST PRIOR ART? DESCRIBE DIFFERENCES IN YOUR INVENTION COMPARING CLOSEST PRIOR ART.

The nearest prior art to this invention is European Patent Application #0 251 798 filed 02.07.87. It details a process in which a beta-glucan source (e.g., barley) is treated with amylases to remove the soluble starches then beta-glucanases to prepare beta-glucans having a DP of 3-4.

continued page 2—

*The invention disclosure will not be reviewed by the patent review committee unless a prior art search has been conducted.

1. continued ---

There is currently much interest in the use of high intensity, low calorie sweeteners to replace sucrose. These are hundreds or thousands of times as sweet as sucrose, so lesser amounts are needed to gain the same level of sweetness. However, these sweeteners fail to provide other functional properties, such as bulk and texture, in addition to sweetening. Therefore, a bulking agent may be used to provide the other properties of sucrose. When this bulking agent contains less utilizable calories than sucrose it may be used to reduce the calories of food. In the case of dessert-type foods sucrose can be the major dry ingredient, thus a caloric reduction would be correspondingly large.

As examples of the invention guar and tamarind seed gums have been enzymatically depolymerized, using Gamanase (a galactomannase) and Celluclast (a mixture of cellulases), respectively. Both enzyme preparations are commercial products manufactured by Novo Enzymes. The resulting solution filtered to remove insoluble contaminants (e.g., proteins, insoluble celluloses, etc.) and the filtrate dried. The dried product contains a range of low to medium molecular weight polysaccharides usable as a low-calorie sucrose-like bulking agent.

2. continued ---

The invention described here overcomes the difficulties in utilizing gums as bulking agents. Enzymes are used to depolymerize the gums. With the shorter polymers and lower viscosity, the gums can be used at useful sucrose replacement levels, such as 15% of the weight (50% replacement of sucrose) of a typical yellow cake. The advantage of these products over current bulking agents is the balance between functionality and digestibility. No other bulking agent produced from natural heteropolysaccharides provides both of these benefits.

3 (c) continued ---

A major difference between our invention and this prior art are the use of the soluble heteropolysaccharide sources (e.g., guar, locust bean gum and tamarind) as the base material for the preparation of our bulking agent. Guar and locust bean are composed of an alpha-1,4-linked mannan backbone with repeating single-unit galactose side chains. While tamarind consists of a beta-1,4-linked glucose backbone containing alternating xylose/galacto-xylose side chains. The prior art bases its products on the beta-glucan component of grain. The claims of the prior art require their bulking agent to be composed of mainly beta-1,3 or beta-1,4 linked tri- or tetraglucans, with the possibility of minor impurities consisting of larger or smaller glucose polymers. Another difference is that our invention contains, as the product, larger oligosaccharides (e.g., a DP of 2-15 for the tamarind product and even a larger range for the guar) than those claimed in the prior art.

4. ESTIMATE OF SALES POTENTIAL OF NEW PRODUCT OR PROCESS: WHAT IS LIKELY TO BE ITS MAIN FIELD OF USE?

5. IF THE IDEA RESULTS IN A PATENT, HOW WOULD WE DETECT INFRINGEMENT?

6. ON WHAT DATE WAS THE INVENTION FIRST CONCEIVED? INDICATE NOTEBOOK ENTRY OR OTHER WRITTEN RECORD AND ATTACH PHOTOCOPY OF DOCUMENT.

7. ON WHAT DATE WAS THE PROCESS FIRST PERFORMED OR THE PRODUCT FIRST PRODUCED?

8. IF THE PRODUCT OF THE INVENTION HAS BEEN SOLD, OFFERED FOR SALE, OR THE PROCESS USED COMMERCIALY, STATE WHEN AND WHERE. IF THE PRODUCT OF THE INVENTION HAS BEEN SAMPLED FOR EVALUATION, STATE WHEN AND WHERE.

9. REMARKS:

Signature of Inventor/s:
(PLEASE PRINT OR TYPE
NAME UNDER SIGNATURE)

Chung-wai Chiu
Chung-wai Chiu

Matthew J. Henley
Matthew J. Henley

James P. Zallie
James P. Zallie

Read and Understood by (Witness)

Morton W. Rutenberg
Morton W. Rutenberg

S

Date: _____, 19__

NS260R2